

JUL 27 2005
K051488

Revised



MEDICINELODGE, INC.

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

<i>Classification Name:</i>	Implantable Clip
<i>Classification:</i>	21 CFR §878.4300, Class II
<i>Common and Usual Name:</i>	Suture Fixation Device
<i>Proprietary Name:</i>	MedicineLodge ZipKnot™

Predicate Device

ULTRABRAID™ (#K041216) currently marketed by Smith & Nephew (Andover, MA).

Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The MedicineLodge ZipKnot™ is indicated for use in approximation and/or ligation of soft tissues using USP #2 braided polyethylene surgical suture.

The MedicineLodge ZipKnot™ consists of a Polyetheretherketone (PEEK) button threaded with high strength polyethylene suture Threaders and housed in a polypropylene Threader Pod. The suture Threaders are used to route the suture through a series of holes in the ZipKnot™. The holes are designed in such a way as to allow suture to be pulled through the button in one direction but lock the suture if pulled in the opposite direction. Once suture is threaded through the button it can be advanced down the suture arms using the same techniques used in both open and endoscopic surgery when tying sliding surgical knots. Once the ZipKnot™ is in place the excess suture ends are trimmed.

The MedicineLodge ZipKnot™ will be provided sterile for single-use (ASTM 4169), packaged individually in a double tyvek pouch. The device will be sterilized by Gamma irradiation (EN 552) or Ethylene Oxide (EN550) including limits for Ethylene Oxide residuals and validated to a sterility assurance level (SAL) of 10^{-6} . The device is biocompatible per ISO-10993 and G95-1.

The MedicineLodge ZipKnot™ is equivalent in intended use, safety, and efficacy to the predicate device. The subject device was shown to have substantially equivalent performance when compared to the predicate device.

The MedicineLodge ZipKnot™ is considered substantially equivalent to Smith & Nephew ULTRABRAID™.

Contact: M. Mary Sinnott, B.Sc.N, M.S.
Project Engineer
MedicineLodge, Inc.
180 South 600 West
Logan, UT 84321
(435) 753-7675 ext. 15

Date: _____



JUL 27 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. M. Mary Sinnott, B.Sc.N.
Project Engineer
MedicineLodge, Inc.
180 South 600 West
Logan, Utah 84321

Re: K051488
Trade/Device Name: MedicineLodge ZipKnot™
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable polyethylene terephthalate surgical suture
Regulatory Class: II
Product Code: NVH
Dated: June 3, 2005
Received: June 13, 2005

Dear Ms. Sinnott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K051488

Revised

INDICATIONS FOR USE

510(k) Number (if known): K051488

Device Name: MedicineLodge ZipKnot™

Indications for Use:

The MedicineLodge ZipKnot™ is indicated for use in approximation and/or ligation of soft tissues using USP #2 braided polyethylene surgical suture.



(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number

K051488

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)